UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

MICHAEL A. HAPPEL,	
Plaintiff,	**Civil Action No.**
v.	
COOK GROUP, INC.; COOK MEDICAL INCORPORATED; COOK MEDICAL, LLC., COOK INCORPORATED;	**JURY TRIAL DEMANDED**
Defendants.	

COMPLAINT

COMES NOW Plaintiff, who by and through the undersigned counsel hereby submits this Complaint and Jury Demand against COOK GROUP, INC., COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK MEDICAL, LLC, and COOK INCORPORATED, hereinafter collectively referred to as "Cook" and/or "Defendants" for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from Plaintiff's injuries from his inferior vena cava ("IVC") filter manufactured by Defendants. In support of this Complaint, Plaintiff alleges the following:

INTRODUCTION

1. This is an action for damages against COOK GROUP, INC., COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK MEDICAL, LLC, and COOK INCORPORATED, hereinafter collectively referred to as "Cook" and/or "Defendants."

2. The allegations, claims and theories of recovery relate to the Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion and/or

distribution of their unsafe medical devices known as Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook Celect Vena Cava Filter, and Cook Celect Platinum, hereinafter "Cook IVC Filters" or "Cook's IVC Filters."

3. Cook IVC Filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including: tilting, perforation, fracture, breakage and migration.

4. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with their devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of its IVC Filters.

5. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as a safe medical device when in fact Cook had reason to know, and/or did know, that its IVC Filters were not safe for their intended purposes, and that its IVC Filters caused serious injury and death.

6. At all times relevant to this action, Cook is and was strictly liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

7. As a direct and proximate result of having Defendants' Celect IVC Filter implanted in him, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to

be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the Celect IVC filter's defects.

PARTIES

Plaintiff

8. Plaintiff MICHAEL A. HAPPEL ("Mr. Happel" or "Plaintiff") is a citizen and resident of Manhattan, New York County, New York.

9. Mr. Happel was implanted with a Cook Celect IVC Filter by Dr. DARREN B SCHNEIDER, M.D., at NY Presbyterian The University Hospital of Columbia and Cornell October 15, 2014.

10. On June 18, 2024 the results of a CT scan showed a piece of metal, approximately the length of a toothpick, in the right ventricle of the heart. Mr. Happel immediately goes to the emergency room at Weil Cornell based on the recommendation of Dr. Feuerbach. On June 20, 2024, Dr. Christopher Lau performed a pericardial window heart surgery at Weil Cornell to remove the piece of metal in the heart. Dr. Lau was unable to remove the piece of metal from the heart. On June 26, 24 Mr. Happel underwent open heart surgery to remove the foreign body by Dr. Christopher Lau at Weil Cornell. Dr. Lau successfully removed the piece of metal from the heart. On October 22, 2024, Mr. Happel underwent IVC filter retrieval with fluoroscopic guidance. The filter was captured, collapsed into the sheath, and removed.

11. Mr. Happel has suffered anxiety, fear, depression, and pain as a result of his injuries caused by the Celect IVC Filter implanted in him.

Defendants

12. Defendant Cook Group, Incorporated is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Defendant Cook Group, Incorporated regularly conducts business in the State of New York, and is authorized to do so. Defendant Cook Group, Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

13. Defendant Cook Group, Incorporated is the parent company of Defendant Cook Medical, Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant Cook Group, Incorporated regularly conducts business in the State of New York and Indiana, and is authorized to do so. Defendant Cook Medical, Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

14. Defendant Cook Group, Inc. is the parent company of Defendant Cook Medical LLC and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of New York, and is authorized to do so. Defendant Cook Medical, LLC may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

15. Defendant Cook Group, Inc. is the parent company of Defendant Cook Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of New York, and is authorized to do so. Defendant Cook

Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

16. At all times alleged herein, the Cook defendants include any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

17. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology and surgical products throughout the United States and around the world. Cook's product at issue in this matter is the Celect Vena Cava Filter which is used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

TAG-ALONG ACTION FOR COOK MEDICAL, INC IVC FILTERS MDL DOCKET NO. 2570

18. This action arises out of injuries sustained while being implanted with a Cook Gunther Tulip inferior vena cava filter. This action should be transferred to Cook Medical, Inc., IVC Filters Marketing, Sales Practices and Products Liability Litigation MDL Docket No. 2570, as a tag-along action. The plaintiff consents to transfer by the Judicial Panel on Multidistrict Litigation.

JURISDICTION AND VENUE

19. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs.

20. Defendants have significant contacts with this federal judicial district therefore

they are subject to the personal jurisdiction of the Court in this district. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this federal judicial district and therefore, pursuant to 28 U.S.C. § 1391(b), venue is proper in this district.

FACTUAL BACKGROUND

21. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' products include the Cook Celect Vena Cava Filter and the Gunther Tulip Filter (collectively referred to herein as "Cook Filters"), which are introduced via a coaxial introducer sheath system. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or their components under Section 510(k) of the Medical Device Amendment.

22. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective.

(Emphasis in original).

23. In *Medtronic, Inc. v. Loehr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contrast to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

24. An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

25. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters, is designed to prevent thromboembolic events.

26. The Cook Filters are retrievable filters.

27. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

28. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

29. At all times relevant hereto, the Cook Filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew their Cook Filters were defective and knew that defect was attributable to the design's failure to withstand the

normal anatomical and physiological loading cycles exerted *in vivo.*

30. A retrospective review of all Cook Gunther Tulip Filters and Cook Celect filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept. 4, 2008 Technical Note).

31. A retrospective review of 115 patients who underwent Cook Celect IVC filter insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to hook endothelialization continues to be an issue with this filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

32. In a review of clinical data related to 73 patients who had Celect IVC filters implanted between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

33. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March

30, 2011 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epic 2011 Mar 30. The authors concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

34. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip and Celect IVC filters and all titled filters also demonstrated vena caval perforation. Defendants knew or should have known that their IVC filters were more likely than not tilt and to perforate.

35. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients and/or Plaintiff that their Cook Filters were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true**.**

36. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support long or short to safety and/or efficacy.

37. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

38. The Cook Filters are constructed of conichrome.

39. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

40. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

41. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

42. The Cook Filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

43. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

DEFENDANTS MADE SPECIFIC MISREPRESENTATIONS AND CONCEALED MATERIAL FACTS REGARDING THE SAFETY AND EFFICACY OF THE CELECT IVC FILTER BASED ON WHAT THEY KNEW OR SHOULD HAVE KNOWN

44. As early as 2002, Arne Molgaard-Neilsen (one of Cook's engineers responsible for the development of Cook's IVC filters) explained that if Cook removed or released the "petals" from the Gunther Tulip IVC filter, the filter would have an increased propensity to perforate.

45. As Cook began to evaluate the design of the Celect IVC filter, it concluded in 2006 that the safety concerns with removing the petals of the Tulip filter to create the Celect outweighed the benefit of doing so. This information was included in an "Executive Summary" prepared for Cook's executives.

46. As soon as the Celect was released on the market, internally Cook had grave concerns regarding the Filter's propensity to perforate.

47. In March of 2008, Annette Lunberg advised Cook's Head of Global Marketing about the rising concern with the increasing rate of Celect perforation complaints.

48. Lykke Iversen (another Cook employee) confirmed the complaint rate for Celect perforations was 15 times higher than the perforation rate for the Tulip.

49. Around this same time, Cook internally believed that perforation was the "Achilles Heel" of the Celect filter.

50. Cook concealed each this data from Plaintiff and the Medical and Scientific Communities.

A. Cook affirmatively concealed the true results of the Celect filter's only human study from Plaintiff and the Medical and Scientific Communities.

51. When reporting the results of the only human trial regarding the use of the Celect filter, Cook falsely reported that no patient experienced a perforation or penetration associated with the filter's use.

52. The MEDI Director of Scientific Affairs for Venous Therapies (Jen Brown) authored a report of this clinical study for publication in a peer-reviewed medical journal. In that report, she falsely reported that no perforations occurred in the study when in fact there were a number of perforations.

53. Furthermore, Cook used a definition of "perforation" for the study's investigators

to use when recording whether perforations exist (i.e., requiring hemorrhage or hematoma to qualify), but changed that definition for publication (i.e., claiming that a perforation is any strut outside the wall of the IVC). Cook concealed this semantic sleight of hand from Plaintiff and the Medical and Scientific Communities.

54. Cook also concealed DVT, IVC thrombosis, and the narrowing of the IVC; each of these adverse events were reported by the study's investigators.

55. Harlan Krumholtz, M.D. has opined that the study had a flawed design, was poorly conducted, had poor outcome assessment, contained selective and misleading reporting, withheld critically important safety information, and misrepresented the data.

56. Cook's VP of Regulatory Affairs (Ted Heise) and Jen Brown were aware of and actively concealed the flawed design of the study.

57. Cook's marketing department (though Bruce Fleck and others) forwarded the published study—containing each of the misrepresentations and concealments noted above—to the medical and scientific communities, demonstrating Cook's intent to promote sales of the Celect by concealing critical safety information.

B. Celect's "Instruction for Use" perpetuated the dangerous misinformation and concealment contained in the only human trial of the filter.

58. The Celect IFU states there were no device-related major adverse events and **zero** perforations in the only human study of the filter, thus concealing the perforations and other safety concerns that were shown through the study.

59. The IFU concealed that Cook was aware of the increasing trend of symptomatic perforations as demonstrated by their internal compilation of adverse event reports.

60. Cook concealed it was aware of the propensity of the Celect to perforate/penetrate the IVC wall occasioned by the design change from the Tulip to Celect (e.g., removing the

"petals"). Cook concealed from the IFU its own information regarding the nature, frequency, ad severity of known failure modes and adverse events associated with the Celect filter.

61. Cook chose not to update the Celect IFU to include any of this information despite the fact that it continued to receive information demonstrating the dangers of the filter.

62. The IFU is provided along with the sale of any Celect filter and is available for review of Plaintiff and the Medical and Scientific communities.

C. Cook continued to aggressively market the Celect filter as efficacious without any evidence of efficacy.

63. As early as 2007, Cook's Director of Reimbursement/Medical Science Officer (James Gardner, M.D.) alerted the company that there was no evidence that IVC filters actually work: "my greatest concern at the moment is that payers are going to take a good, hard look at IVC filter placement and whether any clinical evidence exists to demonstrate it really saves lives or improves patient outcomes in other ways."

64. Cook concealed this fact from Plaintiff and the Medical and Scientific Communities.

65. In 2008, Dr. Gardner again expressed that there is no evidence to demonstrate IVC filters are efficacious: "My concern, which I've shared with a couple of you over the last couple of years, is that one day the payers (Medicare, Medicaid, commercial plans, etc.) are going to realize they are spending an increasing amount of money on the placement and retrieval of IVC filters and that there's not a lot of clinical evidence that demonstrates these filters actually improve patient outcomes."

66. Dr. Gardner went on to say that the only way to make that determination would be to conduct a clinical trial, but "I'm not suggesting we go down that path." Instead, Dr. Gardner states, "I am keeping a close eye on payers' medical policies to see if/when this hits their radar

screens."

67. Cook concealed this fact from Plaintiff and the Medical and Scientific Communities.

68. In 2009, Dr. Gardner raised his concerns again: "as Cook's Director of Reimbursement, I've been very surprised that payers in this country haven't raised questions about whether they should pay for IVC filter placements (and retrievals), given the # of procedures being performed and the paucity of data supporting these procedures."

69. Cook concealed this fact from Plaintiff and the Medical and Scientific Communities.

70. Dr. Gardner shared the same information again in 2010. Cook concealed this fact from Plaintiff and the Medical and Scientific Communities.

71. In 2013, Dr. Gardner, once again, confirmed, "There's never been strong clinical evidence supporting IVC filter use."

72. Cook concealed this fact from Plaintiff and the Medical and Scientific Communities.

73. Throughout the Celect's life-cycle, Cook concealed that the use of the filter was **not** associated with a significant decrease in the rate of subsequent PE, PE related mortality, or all-cause mortality.

D. Cook's marketing strategy was designed to stimulate sales without reference to (and, in fact, despite) safety concerns and to continue concealing important information about Celect-related adverse events.

74. Cook representative Rita Harden confirmed that she and others (including Tom Roberts) were aware of a series of adverse events which should have been reported to the FDA but were not – by Cook's intention and design.

75. This concealment served to depress the information available to the medical and scientific communities by lowering the number of adverse events in the MAUDE database.

76. Then, Bruce Fleck encouraged Cook's sales force to advise the medical community to access the MAUDE database and note the Celect's adverse events were lower compared to Cook's competitors.

77. The Cook marketing plan was designed to stimulate sales and influence the physician decision making process by emphasizing the "fear factor" and encouraging the sales force to deflect physician questions about the company information regarding adverse event experience associated with the Celect product while suggesting that use of the Celect product might be used in bariatric cases, orthopedic surgery cases, cancer cases, and other cases for which the use of the product had not been cleared.

78. Cook then concealed that the personal income, career advancement, and personal success of its sales force was tied directly to the number of filters sold.

E. Cook suppressed, omitted, concealed, and failed to disclose material information about the known adverse events and lack of efficacy in the Celect "Patient Guide."

79. The patient guide conceals the known nature, frequency, and extent of serious failure modes and associated adverse events associated with the Celect filter.

80. The patient guide conceals the severity and frequency of embedded filters and the associated progressive injury Cook knew to be associated with the Celect filter.

81. The patient guide conceals the know frequency of penetration/perforation into other organs associated with the Celect filter.

82. The patient guide conceals the adverse event reports of perforation associated with the Celect to be 15 times that of the Tulip.

83. The patient guide conceals that the reported deaths associated with use of the Celect filter exceed that reported with competitor products.

84. This concealment deprived Plaintiff and his physician of the data needed to perform an informed risk/benefit analysis. This concealment deprived Plaintiff of the information he needed to discover a potential cause of action against Cook.

F. Cook pulled the Celect from the market and concealed from Plaintiff and the Medical and Scientific Communities that the decision was made based upon the high rate of perforation.

85. As early as May 2010, Cook began an effort to re-design the Celect to address the filter's high perforation rate.

86. While continuing its aggressive marketing of the Celect Filter, Cook concealed its internal belief and understanding that the filter had to be re-designed to address the nature, severity, and frequency of adverse events associated with the filter.

87. On October 1, 2014, Cook (through its Marketing Executive, Bruce Fleck) sent a letter to the medical community stating that Cook would be discontinuing production of the Celect.

88. But, Cook misrepresented the reason for the discontinuation of the Celect and further concealed from the Plaintiff and the medical and scientific communities the true reason the Celect was being pulled – the high rate of adverse events

89. These aforementioned representations and concealments were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, implant and/or attempt retrieval of the Defendants' IVC filters.

FRAUDULENT CONCEALMENT, DISCOVERY RULE, EQUITABLE ESTOPPEL AND WAIVER, AND TOLLING OF THE STATUTE OF LIMITATIONS

90. Defendants are equitably estopped from claiming that Plaintiff's claims are barred by the statute of limitations in the present action.

91. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with Cook's Celect IVC Filter, including but not limited to: tilting, perforation, fracture, breakage and migration.

92. Cook Defendants' sales representative who sold Cook's Celect IVC Filter to Plaintiff's implanting physician concealed the above-referenced risks shortly before and/or during Plaintiff's implantation procedure.

93. Cook Defendants' sales representative who sold Cook's Celect IVC Filter to Plaintiff's implanting physician concealed the above-referenced risks at all time relevant after Plaintiff's implantation procedure through the present.

94. Prior to Plaintiff's implantation procedure, his implanting physicians attended an event(s) where they were trained on how to implant Cook's Gunther Celect Filter into their patients, including Plaintiff. During these training session(s) or event(s), Defendants made affirmative representations and/or concealments of the above-referenced risks they knew about.

95. Plaintiff's implanting physician(s) reasonably relied on Defendants affirmative representations and/or concealments of the above-referenced risks because they recommended implantation of their Celect IVC Filter to Plaintiff.

96. As a result of Defendants' actions, Plaintiff and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence,

that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

97. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with a Cook IVC Filter and the harm Plaintiff suffered as a result.

98. Additionally, the accrual and running of any applicable statute of limitations have been tolled by reason of Defendants' fraudulent concealment.

99. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

100. Additionally, the limitations period ought to be tolled under principles of equitable estoppel or tolling.

COUNT I: NEGLIGENCE

101. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

102. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including its Cook Celect IVC Filter.

103. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Plaintiff and to those people receiving their Celect IVC Filter.

104. At the time of manufacture and sale of the Cook Celect IVC Filters, the Cook Defendants knew or reasonably should have known the Cook Celect IVC Filter:

a. was designed and manufactured in such a manner so as to

present an unreasonable risk of fracture of portions of the device;

b. was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. was designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena cava wall.

105. Despite the aforementioned duty on the part of the Cook Defendants, they committed one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Celect IVC Filter, specifically their incidents of fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufactured a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

c. unreasonably and carelessly designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

106. As a direct and proximate result of the Cook Celect IVC Filter's defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook Celect IVC Filter's defects.

107. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Plaintiff and healthcare professionals about the increased risk of serious injury and death caused by their defective Celect IVC filter.

108. WHEREFORE**,** Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT II: NEGLIGENCE PER SE

(Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

109. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

110. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Cook Celect IVC Filter.

111. By reason of its conduct as alleged herein, Cook violated provisions of statutes and regulations, including but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331 and 352, by misbranding its Cook Celect IVC Filter;

b. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 in making statements and/or representations via word, design, device or any combination

thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook Celect IVC Filter to which the labeling and advertising relates;

c. Defendants violated the 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of their Cook Celect IVC Filter;

d. Defendants violated the 21 C.F.R. §801 in mislabeling their Cook Celect IVF Filter as to safety and effectiveness of their products and by failing to update their label to reflect post-marketing evidence that Cook Celect IVC Filter was associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. Defendants violated the 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

f. Defendants violated the 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when their Cook Celect IVC Filter was no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and

g. Defendants violated the 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions.

112. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT III: STRICT PRODUCTS LIABILITY - DESIGN DEFECT

113. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

114. Plaintiff brings a design defect claim based on strict products liability theory.

115. The Celect IVC Filter as designed posed a substantial likelihood of harm.

116. The reasons that Defendants' Celect IVC Filter as designed posed a substantial likelihood of harm include, but are not limited to:

a. was designed in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. was designed so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. was designed to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. was designed so as to present an unreasonable risk of perforation and damage to the vena cava wall.

117. It was feasible to design the product in a safer manner because Defendants:

a. designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

b. designed a product that presented a risk of harm to the Plaintiff and others similarly situated in that it was prone to fail.

118. As a direct and proximate result of the Cook Celect IVC Filter's design defects, as described herein, the defective design was a substantial factor in causing Plaintiff's injuries.

119. Plaintiff suffered permanent and continuous injuries, pain and suffering, disability

and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook Celect IVC Filter's defects.

120. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their design of their Celect IVC Filter resulting in the product to be unreasonably dangerous and defective.

121. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT IV: MANUFACTURING DEFECT

122. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

123. Plaintiff brings a manufacturing defect claim based on negligence and/or strict liability theories.

124. The Cook Celect IVC Filter implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Defendants' manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff.

125. Upon information and belief, Defendants failed to manufacture the Cook Celect IVC Filter that was implanted in Plaintiff as manufactured, as discussed below:

a. Defendants manufactured/and or sold the Cook Celect Filter in such a

manner so that the exterior surface of the Filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail;

b. Defendants manufactured and/or sold their Cook Celect IVC Filter and said filter did not conform to representations made by the Defendants that the device was safe and effective, provided a permanent solution to pulmonary embolism, would not migrate, fragment, tilt, and/or perforate when it left the Defendants' control;

c. Defendants manufactured and/or sold their Cook Celect IVC Filter which was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Celect Filter's design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Defendants' control; and

d. Defendants manufactured and/or sold their Cook Celect IVC Filter when they deviated in a material way from the design specifications, formulas or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left the Defendants' control.

126. Further, Defendants' marketing of their Cook Celect IVC Filter was false and/or misleading since the device is not safe and effective; does not provide a permanent solution to pulmonary embolism; and otherwise migrates, fragments, tilts, and/or perforates the IVC.

127. Plaintiff, through his attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

128. Defendants' Celect filter was unfit and unsafe for use by users, including Plaintiff, as it posed an unreasonable and extreme risk of injury to Plaintiff, and accordingly Defendants

breached their expressed warranties and the implied warranties associated with the product.

129. As a direct and proximate result of the Cook Celect IVC Filter's manufacturing defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Cook Celect IVC Filter's defects.

130. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their manufacturing the Celect IVC Filter that resulted in the product being unreasonably dangerous and defective.

131. WHEREFORE**,** Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT V: FAILURE TO WARN

132. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

133. Plaintiff brings a failure to warn claim based on negligence and/or strict liability theories.

134. Defendants had a duty to individuals, including the Plaintiff and his implanting physician, to warn of latent dangers resulting from intended or reasonably foreseeable unintended uses of the Celect IVC filter and use reasonable care in providing adequate warnings for their Celect IVC Filter.

135. Defendants negligently failed to warn or instruct the Plaintiff and/or his implanting physician of known subjects including, but not limited to, the following:

a. Cook Celect IVC Filter contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury;

b. information provided by Cook to the medical community and to consumers concerning the safety and efficacy of their Celect IVC Filter did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer;

c. at all times relevant hereto, the Cook Celect IVC Filter was dangerous and presented a substantial danger to patients who were implanted with the Cook Celect IVC Filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not have recognized the potential risks and dangers the Cook Celect IVC Filter posed to patients, because their use was specifically promoted to improve health of such patients, including Plaintiff;

d. had adequate warnings and instructions been provided, Plaintiff would not have been implanted with Cook Celect IVC Filter, and would not have been at risk of the harmful injuries described herein. The Defendants failed to provide warnings of such risks and dangers to the Plaintiff and his medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury

and/or death associated with and/or caused by Cooks' Celect IVC Filter;

e. Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury associated with and/or caused by Cook Celect IVC Filter;

f. Plaintiff, individually and through his implanting physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants; and

g. Defendants had a continuing duty to warn Plaintiff and his implanting physicians of the dangers associated with the subject product.

136. Defendants' IFU for the Celect IVC Filter product is defective, deficient, and/or insufficient because it does not warn of every single injury experienced by Plaintiff and the causes of those injuries.

137. Defendants' IFU for the Celect product is defective, deficient, and/or insufficient because it does not list known adverse events and risks that caused the injuries that Plaintiff sustained.

138. Defendants' Cook Celect IVC Filter product IFU is deficient because it fails to detail the extent and frequency of known complications, including migration, titling, fracture and perforation, experienced by Plaintiff.

139. At a minimum, if Defendants provided and conveyed to Plaintiff's implanting physician all known defective propensities, risks, adverse events, and contraindications of the Celect product, this learned intermediary would have considered this information in the consent process with Plaintiff. No reasonable physician would knowingly implant a defective product or a product that would not work or a product that would exhibit the above-referenced defective propensities and cause associated injuries in their patients. The same can be said for Plaintiff's

implanting physician. Ultimately, it was Plaintiff's decision as to whether or not he would consent to the Celect product implanted in him, and he would have not consented to the Celect being implanted in him.

140. If Defendants provided Plaintiff's implanting physician with adequate warnings in the Celect IFU or other materials provided, Plaintiff's implanting physician would have heeded those warnings.

141. If Plaintiff's implanting physician was adequately warned by being informed of all known risks, adverse events, and contraindications of the Celect product, Plaintiff's implanting physician would have warned Plaintiff of the same.

142. Plaintiff's implanting physician would have changed his consent process and/or not recommended or prescribed Defendants' Celect product to Plaintiff if Defendants had given proper and adequate warnings to him.

143. If Plaintiff was properly consented to the Celect product by being informed of all relevant risks, adverse events, and contraindications of the device – which he was not – he would not have consented to have the Celect product implanted in him and the sequalae and injuries he experienced.

144. Plaintiff relied on his implanting physician to inform him about all material facts regarding the risks, adverse events, and contraindications of the Celect.

145. Plaintiff used the the Celect IVC Filter in a reasonably foreseeable manner.

146. As a direct and proximate result of the Defendants' failure to warn and the Cook Celect IVC Filter's defects, as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal

life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills, both past and future, related to care because of the Cook Celect IVC Filter's defects.

147. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their negligent failure to warn and/or adequately warn the Plaintiff and his healthcare, implanting professionals about the increased risk of serious injury and death caused by their defective Celect IVC Filter.

148. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT VI: BREACH OF EXPRESS WARRANTY

149. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

150. Plaintiff, though his medical providers, purchased a Cook Celect IVC Filter from the Cook Defendants.

151. At all times relevant to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cook Celect IVC Filters).

152. At the time and place of sale, distribution and supply of the Cook Celect IVC Filter to Plaintiff (and to other consumer and the medical community), the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the Instructions for Use ("IFU"), that the Cook Celect IVC Filter was safe, well-tolerated, efficacious, and

fit for its intended purpose and was of marketable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

153. At the time of Plaintiff's purchase from Defendants, the Cook Celect IVC Filter was not in a merchantable condition and Defendants breached their expressed warranties, in that the filter:

a. was designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. was designed in such a manner so as to result in a unreasonably high incident of injury to the organs of its purchaser; and

c. was manufactured in such a manner so that the exterior surface of the Cook Celect Filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

154. By and through commercial documents that may have been provided to Plaintiff, Defendants expressly warranted that the Celect filter was safe and effective.

155. Defendants breached the above-referenced express warranties which are otherwise false.

156. Plaintiff is in privity with Defendants as the third-party, intended beneficiary of the Celect product.

157. Plaintiff, by and through his implanting physician(s), relied on the above-referenced warranties in consenting to the implant procedure.

158. Defendants' warranties were made to benefit Plaintiff as a patient – not to benefit his implanting physician(s) or the hospital Defendants sold the Celect to – such that Plaintiff is the intended consumer of the Celect device.

159. Defendants breached these express warranties because the Celect product implanted in the Plaintiff was unreasonably dangerous and defective, as described herein, and not as Defendants had represented. The above-referenced warranties were breached or are otherwise false, and they ran with the product.

160. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective Celect product in Plaintiff, placing Plaintiff's health and safety in jeopardy.

161. As a direct and proximate result of the Cook Celect IVC Filter's defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has suffered emotional trauma, harm, and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the Celect IVC Filter's defects.

162. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their breach express warranty.

163. WHEREFORE**,** Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT VII: BREACH OF IMPLIED WARRANTY

164. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

165. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold their Celect IVC Filter.

166. At all relevant times, the Defendants intended their Celect IVC Filter be used in the manner that Plaintiff in fact used it.

167. Defendants impliedly warranted their Celect IVC Filter to be of merchantable quality, safe and fit for the use for which the Defendants intended it and for which Plaintiff in fact used it.

168. Defendants breached their implied warranties as follows:

a. Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that their Cook Celect IVC Filter would cause harm;

b. Defendants manufactured and/or sold their Cook Celect IVC Filter and said filter did not conform to representations made by the Defendants that the device was safe and effective, provided a permanent solution to pulmonary embolism, would not migrate, fragment, tilt, and/or perforate when it left the Defendants' control;

c. Defendants manufactured and/or sold their Cook Celect IVC Filter which was more dangerous than an ordinary consumer would expect when used in an intended or

reasonably foreseeable manner, and the foreseeable risks associated with the Cook Celect Filter's design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Defendants' control; and

d. Defendants manufactured and/or sold their Cook Celect IVC Filter when

they deviated in a material way from the design specifications, formulas or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left the Defendants' control.

169. Further, Defendants' marketing of their Cook Celect IVC Filter was false and/or misleading since the device is not safe and effective; does not provide a permanent solution to pulmonary embolism; and otherwise migrates, fragments, tilts, and/or perforates the IVC.

170. Plaintiff, through his attending physicians, relied on these representations in determining which IVC filter to use for implantation in the Plaintiff.

171. Defendants' Celect filter was unfit and unsafe for use by users, including Plaintiff, as it posed an unreasonable and extreme risk of injury to Plaintiff, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

172. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries and damages as alleged.

173. The Plaintiff, by and through his implanting physicians as his learned intermediaries, relied upon Defendants' implied warranties of merchantability in consenting to have the Celect product implanted in him.

174. Plaintiff was the intended third-party beneficiary of Defendants' Celect product since Defendants knew Plaintiff's implanting physicians intended to implant the Celect IVC Filter in Plaintiff.

175. Privity of contract is inferred since Defendants' warranties of the Celect IVC Filter ran with the product.

176. Defendants further breached their implied warranty that the Celect that was

implanted in Plaintiff is a permanent device and would not need to be retrieved.

177. As a direct and proximate result of the Cook Celect IVC Filter's defects, as described herein, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and has medical bills both past and future related to care because of the Celect IVC filter's defects.

178. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their breaches of implied warranty.

179. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems just and proper.

COUNT VIII: NEGLIGENT MISREPRESENTATION

180. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

181. Defendants had a business and professional duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, the FDA, and the public, that the Celect IVC Filter had not been found to be safe and effective.

182. Defendants maintained a business and professional duty to Plaintiff and his implanting physician to inform them of the defective propensities and harmful effects of their Celect IVC Filter.

183. Defendants maintained a business and professional duty to Plaintiff and his implanting physician to accurately represent the qualities and efficacy of their Celect IVC Filter.

184. As set forth above in ¶¶43-88, Plaintiff has alleged that Defendants made specific misrepresentations and concealed material facts regarding the safety and efficacy of the Celect IVC Filter. Pursuant to Fed. R. Civ. P. 9(b), Plaintiff has pled these allegations with specificity.

185. The aforementioned misrepresentations were material.

186. Defendants knew or should have known that the aforementioned misrepresentations were untrue.

187. At all times material, including immediately before and during the implantation consent process between Plaintiff and his implanting physician, Defendants breached their duty to inform Plaintiff's implanting physician, regulatory agencies (including the FDA), and the public of the risks, adverse events, and contraindications of the Celect IVC Filter which came to, or should have come to, Defendants' attention.

188. Defendants failed to exercise ordinary care in the representations concerning the Celect IVC Filter while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Celect IVC Filter's high risk of unreasonable, dangerous, adverse side effects.

189. The facts misrepresented by Defendants to Plaintiff and his implanting physician were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Celect IVC Filter.

190. Plaintiff and Plaintiff's implanting physician intended to rely and act upon the information provided by Defendants.

191. Plaintiff reasonably relied on Defendants' misrepresentations to his detriment.

192. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX: COMMON-LAW FRAUD

193. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

194. As set forth above in ¶¶43-88, Plaintiff has alleged that Defendants made specific false statements and concealed material facts regarding the safety and efficacy of the Celect IVC Filter. Pursuant to Fed. R. Civ. P. 9(b), Plaintiff has pled these allegations with specificity.

195. The aforementioned representations were material.

196. The aforementioned representations were false.

197. When the Defendants made the representations, Defendants knew that they were false, or made them recklessly, without knowledge of their truth as positive assertions.

198. Defendants made the representations with the intention that the Plaintiff's implanting physician and Plaintiff would act upon them by proceeding with the implantation of the Celect product.

199. Plaintiff's implanting physician and Plaintiff acted in reasonable reliance upon these representations by electing to have the Celect IVC Filter implanted.

200. The false representations made by Defendants to Plaintiff and his implanting physician were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Celect IVC Filter.

201. As a direct and proximate result of having Defendants' Celect IVC Filter implanted in him, Plaintiff has suffered permanent and continuous injuries, pain and suffering,

disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the Celect IVC filter's defects.

202. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X: FRAUDULENT CONCEALMENT

203. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

204. As set forth above in ¶¶43-88, Plaintiff has alleged that Defendants concealed or omitted material facts regarding the safety and efficacy of the Celect IVC Filter. Pursuant to Fed. R. Civ. P. 9(b), Plaintiff has pled these allegations with specificity.

205. Defendants concealed or omitted material facts regarding the risks, adverse events, contraindication from Plaintiff and his implanting physician. These material facts are detailed herein and include: titling, migration, fracture, breakage, and perforation.

206. The Defendants had a duty to disclose. Defendants had duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, the FDA, and the public, that the Celect IVC Filter had not been adequately tested and found to be safe and effective.

207. Defendants had a duty to Plaintiff and his implanting physician to inform them of the defective propensities and harmful effects of their Celect IVC Filter as detailed herein.

208. Defendants had a duty to Plaintiff and his implanting physician to accurately represent the qualities and efficacy of their Celect IVC Filter.

209. Plaintiff's implanting physician and Plaintiff acted in reliance upon these concealed or omitted material fact by electing to have the Celect IVC Filter implanted.

210. These omissions of material fact by Defendants were material because a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Celect IVC Filter.

211. As a direct and proximate result of having Defendants' Celect IVC Filter implanted in him, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the Celect IVC filter's defects.

212. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI: CONSTRUCTIVE FRAUD

213. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

214. As set forth above in ¶¶43-88, Plaintiff has alleged that Defendants made specific fraudulent statements and concealed material facts regarding the safety and efficacy of

the Celect IVC Filter. Pursuant to Fed. R. Civ. P. 9(b), Plaintiff has pled these allegations with specificity.

215. The aforementioned representations were material.

216. The aforementioned representations were false.

217. Defendants had a business and professional duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, the FDA, and the public, that the Celect IVC Filter had not been found to be safe and effective.

218. Plaintiff's implanting physician and Plaintiff acted in reliance upon these representations by electing to have the Celect IVC Filter implanted.

219. The false representations made by Defendants to Plaintiff and his implanting physician were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Celect IVC Filter.

220. As a direct and proximate result of having Defendants' Celect IVC Filter implanted in him, Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost his ability to live a normal life, and will continue to be so diminished into the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills both past and future related to care because of the Celect IVC filter's defects.

221. Defendants maintained a position of superiority over Plaintiff and his implanting physician such that fraud can be inferred even without the requisite intent.

222. As the intended, third party beneficiary of the Celect, a quasi-fiduciary and/or confidential relationship between Plaintiff and Cook Defendants exists.

223. WHEREFORE, Plaintiff demands judgment against Defendants, and each

of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

224. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

225. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed, and sold Defendants' Celect IVC filter to Plaintiff, carelessly and negligently concealed the harmful effects of the Defendants' Celect IVC filter from Plaintiff, and carelessly and negligently misrepresented the quality, safety, and efficacy of the Celect IVC filter.

226. Defendants maintained a duty to Plaintiff and his implanting physician to inform them of the defective propensities and harmful effects of their Celect IVC filter.

227. Defendants maintained a duty to Plaintiff and his implanting physician to accurately represent the qualities and efficacy of their Celect IVC filter.

228. Defendants breach their above-referenced duties owed to Plaintiff and his implanting physician, as further detailed in this Complaint.

229. Plaintiff was clearly within the zone of danger of physical impact of the Celect IVC filter considering it is still implanted in him.

230. Plaintiff reasonably feared for his own safety due to the Celect IVC Filter implanted in him. Plaintiff suffered constant threats to his own personal security as long as Defendants' Celect IVC Filter remained implanted in him.

231. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical

injuries, economic losses, and other damages as a direct result of being implanted with the Celect IVC filter sold and distributed by Defendants and/or because of the nature of their relationship to the individual implanted with the Celect IVC filter.

232. Plaintiff sustained physical injuries, including but not limited to pain and suffering, that were caused by psychological trauma (stress, anxiety, sadness, anger, etc.) related to the Defendants' above-referenced conduct.

233. Plaintiff's above-referenced emotional distress was and is so severe that no reasonable person could have been expected to endure it. Plaintiff's emotional distress was medically diagnosable.

234. Defendants' above-referenced conduct is so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community.

235. Plaintiff was under constant fear that the Celect IVC Filter could tilt, fracture, break, migrate and/or perforate his vein or other bodily organs.

236. Plaintiff now knows that the Celect IVC Filter that was in his body could tilt, fracture, break, migrate and/or perforate his vein or other bodily organs; he was very stressed and anxious since the Celect IVC Filter was behaving this way.

237. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages. As long as Defendants' Celect IVC filter remains implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' Celect IVC filter before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death. Even with successful removal of the defective Celect IVC filter, Plaintiff will still experience permanent injuries caused by the device.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE**,** Plaintiff demands judgment against the Cook Defendants as follows:

A. compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B. restitution and disgorgement of profits;

C. reasonable attorneys' fees;

D. the costs of these proceedings;

E. economic damages;

F. medical monitoring damages;

G. punitive damages; and

H. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: February 7, 2025

Respectfully submitted,

THE LAW OFFICES OF STEVEN GACOVINO, P.C
/s/ *Richard Zgoda Jr.*
Richard Zgoda, Jr. NY Bar #4781506
Steven D. Gacovino
THE LAW OFFICES OF STEVEN GACOVINO P.C.
270 West Main Street
Sayville, NY 11782
Telephone: 631-646-1200
Facsimile: 631-761-0467
rich@gaclawyer.com

WAGSTAFF & CARTMELL LLP
Andrew N. Faes MO Bar #59721
(appearance to be field upon transfer)
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
Tel. (816) 701-1100
Fax (816) 531-2372
afaes@wcllp.com

Counsel for Plaintiff